UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC., ET AL,

Plaintiffs, **CIVIL ACTION NUMBER:**

-vs- **09-00037**

LUPIN PHARMACEUTICALS, INC., ET AL,

Defendants.

Mitchell H. Cohen United States Courthouse
One John F. Gerry Plaza
Camden, New Jersey 08101
December 2, 2011

B E F O R E: **THE HONORABLE ROBERT B. KUGLER**
UNITED STATES DISTRICT JUDGE

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(Open court)
THE DEPUTY COURT CLERK: All rise.
THE COURT: Good morning.
MR. BASSETT: Good morning, your Honor.
10:31 MS. MATTERER: Good morning, your Honor.
MR. KRATZ: Good morning, your Honor.
MR. NOYES: Good morning, your Honor.
MS. JACOB: Good morning, your Honor.
MR. HOCHSTETLER: Good morning, Your Honor.
10:43 THE COURT: Good morning. Have a seat. How is everybody? Good?
MR. BASSETT: Good.
THE COURT: All right. I don't know if I dare to ask this question, but I saw in your papers you had some
10:45 settlement discussions, which apparently didn't have, have not led to a settlement yet. But is that something that you want to pursue at this point, or what do you want to do? Because we've got this motion on. I'm prepared to hear it. It's likely I will rule today on it. I don't know if I'm going to
10:46 be able to issue a written opinion today but if not today, certainly Monday or Tuesday a written opinion. And that I would think would alter settlement positions of some people? You tell me.
MR. BASSETT: Your Honor, I believe from Shionogi's,
10:46 perspective, we have had discussions, but there's nothing more

to discuss at this point until after the Court rules on the motion.

THE COURT: Okay. Okay. Let's start with the appearances of counsel, please. With the plaintiffs. Start with the plaintiffs.

MS. JACOBS: Good morning, Your Honor. For the plaintiff Shionogi, I'm Karen Jacobs Louden from Morris Nichols Arsht and Tunnell from Delaware. We have David Bassett, Christopher Noyes, David Manspeizer, Somil Trivedi from Wilmer Hale.

THE COURT: Thank you. Good morning.

MR. FINEMAN: Good morning, Your Honor. Steve Fineman from Richard, Layton and Finger on behalf of the Watson parties. Sitting at counsel table is Gary Hood from Polsinezli and Shugart. And sitting in the back with me is Matthew Brady from Watson.

THE COURT: Thank you. Good morning. Welcome back.

MS. MATTERER: Good morning, Your Honor. Mary Matterer from Morris James in Wilmington and on behalf of the Mylan defendants and I'm here with Timothy Kratz from the McGuire Woods law firm.

MR. KRATZ: Good morning.

THE COURT: All right.

MR. KIRK: Good morning, Your Honor. Richard Kirk from the Wilmington firm, Bayard PA for the Lupin defendants.

I have a large cast of characters. It's of great interest to us.

My cocounsel are Douglas Hochstetler and Beth Jacob from Schiff Hardin, and their colleagues are Jason Harp and Kelly Morron. And from Lupin itself, Sophia Moontaz and Anthony Romano. And also our New Jersey colleague is Karen Confoy.

THE COURT: All right. Thank you. Anybody else want to put their appearance on the record? No? Okay.

One thing we do need to discuss today, by the way, is where we go from here. I'm sure you're aware that Delaware is now up to speed with their judicial allotment. My question becomes whether this case should go back to Delaware or in Delaware, but whether it goes to a Delaware Judge or I should keep this case. I want to hear your positions on that.

MR. BASSETT: From our perspective, your Honor, it may depend on how you rule on this motion.

(Laughter)

THE COURT: Fair enough. So you want to talk about this afterwards.

MR. BASSETT: Okay.

THE COURT: Okay. Now what I've been trying to do with all my Delaware cases is if I have nothing to do in it, at this point I'd send it back. If it's brand new, I'd send it back. But if I've invested quite a bit of time in it, I've

offered the Delaware Judge is that I'll keep it because I have some familiarity with it, with the attorneys and the facts in the case. I mean you may not agree that I get it right, but at least the new Judge doesn't have to get up to speed on this 00:49 stuff. So I really leave it up to you what you want to do. You all come to Camden. You don't seem to mind. You have a right to go to Wilmington in the case and have it tried there. I will go to Wilmington and try the case there when the time comes if that's what we decide to do.

00:49 Let's talk about it after this motion.

All right. Who is -- are you going to speak for the plaintiffs?

MR. BASSETT: Yes, Your Honor.

THE COURT: Well, okay. This is your motion. 00:49 Obviously you all know the factors that have to be applied, likelihood of success on the merits. Irreparable injury, balance factors, public interest.

So let's start at the beginning. Likelihood of success on the merits. The defendants say they've raised a 00:50 substantial question here as to the patent and whether or not they're violating the patent. They point to the study by Doctor Shepard. So let's start with that.

MR. BASSETT: Sure, your Honor. If I could, I'd like to hand up copies of --

00:50 THE COURT: Sure.

MR. BASSETT: -- slides that we prepared. One for you, your Honor.

THE COURT: Thank you.

MR. HOCHSTETLER: Thank you.

00:50 MS. MATTERER: Thank you.

MR. BASSETT: Your Honor, if I might, before I turn to the likelihood of success on the merits, I'd like to try to, if I could, to address the suggestion in Lupin's brief that Shionogi somehow delayed in bringing this motion and took

00:51 no steps to protect itself. And then I'll turn directly to the question that your Honor has posed about the likelihood of success on the merits.

Your Honor, nothing could be farther from the truth. On June 30, 2011, Lupin and Shionogi entered into a settlement

00:51 and release agreement that required the parties to maintain the status quo. That agreement was in effect until September 30th, 2011 when Lupin for the first time terminated that agreement, launched its generic product and then we filed this motion a couple of days later. Perhaps we can look at

00:51 that time line just quickly. Based on the documents that have been produced in discovery, we now know that Lupin began forecasting for a launch as early as December 2010. And by March 2011, Lupin was planning to launch the generic product as early as June 1st, 2011. But none of that, of course, was

00:52 public information. Now, Lupin --

THE COURT: Why would they make it, necessarily make it public at that time?

MR. BASSETT: Well, I'm not suggesting that they should have made it public, your Honor. But Lupin has suggested in its briefs that we somehow slept or our rights because it was public. And they point to a couple of Wall Street Journal articles.

THE COURT: I know.

MR. BASSETT: The first of which was dated June 22, 2011 in which there was one sentence in which they said that they may launch this year. But what happened right after that, your Honor. That was June 22nd. On June 30th, Shionogi and Lupin entered into the Settlement and Release Agreement that obligated the parties to maintain the status quo, and that stayed in effect until September 30, 2011 just before we filed this motion and just before they launched. They obviously started to make plans for the launch even though they were contractually obligated to maintain the status quo. Lupin planned for an August or October launch, and they maintained a high level of secrecy about all these plans, as one would expect, for what they called this stealth launch. This -- from a company that now suggests to this court, however, that Shionogi should have known that they were going to launch, despite the contractual obligation to maintain the status quo. As early as August, despite being contractually

obligated to maintain that status quo, they were preparing to launch but ran into quality control problems. And we highlighted one of the e-mails that we've been given in discovery that talks about why they couldn't launch this product when they wanted to in August, they were having trouble with their equipment which their own people call a 15 year old piece of junk. That was the problem. That's the reason they didn't launch earlier.

So then in September 7th of this year, the Court and the parties engaged in the Markman Hearing. Lupin again never suggests they're about to launch. And despite still being contracturally obligated to maintain that status quo, on September 23rd, Lupin shipped product from India to the United States in quantities sufficient to satisfy one third of the entire annual market for extended release Metformin. Then came the second of the Wall Street Journal articles. It points to on September 28th a mere two days before Lupin launched its generic product. But what does Lupin say in that article. It says in the next few months they're going to launch their product. On September 29th, Lupin secretly shipped all launch orders and gave truck drivers so-called covert tracking numbers. So that even the truck drivers didn't know where they were going as they took this generic product around the United States before they got the final orders. Then, finally, on September 30th, Lupin for the first

time delivered to Shionogi a letter by hand terminating the Standstill Agreement that had supposedly obligated the parties to maintain the status quo after it had already shipped from India one third of the annual supply and after it had
00:55 delivered around the country so-called covert tracking deliveries. It was over that weekend that we investigated and we filed a preliminary injunction motion. So days later.

So Lupin's argument that Shionogi delayed in seeking injunctive relief, took no steps to protect itself, we
00:55 respectfully suggest should be given no weight by this Court. And I would just note that Lupin and Shionogi have subsequently entered into a second Standstill Agreement which is what brings us here today. We were negotiating the date of this hearing. We agreed to a later date for a preliminary
00:56 injunction hearing based on a second Standstill Agreement which expires at midnight tonight, your Honor.

So, with that time line in mind, I'd now turn to the merits of the P.I. motion. And as you say, the Court is well aware of the standards that apply to a motion for a
00:56 preliminary injunction.

Your Honor, we believe that Shionogi is likely to succeed on the merits of this motion because Shionogi will show that it's likely by a preponderance of an evidence standard that we can show Lupin infringes. Its own product
00:56 label establishes that fact. Lupin is also unlikely to meet

the burden of proving invalidity by clear and convincing evidence. The invalidity argument it makes are based almost exclusively on prior art. It was considered and rejected by the Patent Office. And Shionogi has suffered irreparable harm. We'll get to that later, as you suggest.

First let's turn to the likelihood of success on the merits. As you know, your Honor, to prevail Shionogi need only show a likelihood that Lupin infringes at least one claim of the asserted patent. So we have focused on the 866 Patent.

THE COURT: In claim one. Correct?

MR. BASSETT: Claim Count 1 and Claims 3, your Honor, to be fair. They're virtually identical. Just a little bit narrower time frame for the Tmax element. We need look no further than Lupin's own FDA approved label as evidence of infringement of that Tmax claim element. They have acknowledged that they meet every single element of Claim 1 and Claim 3 of the 866 Patent, but for the Tmax element. And their own FDA proved label addresses that issue directly, as does a study that they submitted to the FDA as part of the Andrx approval. But first and foremost, despite Lupin's, I would say, elaborate attempts to walk away from its own product label, we believe that label alone establishes a likelihood of success on our claim of infringement. But first let's look at the relevant claim language. Claim 1 has various elements but the key element that we're focusing on is

a claim that the dosage form provides a mean time to maximum plasma concentration which is what's called Tmax of the Metformin from 5.5 to 7.5 hours after administration following dinner. And your Honor will recall some discussions about what dinner means and all of that in our context, in the kinds of claim construction. Claim 3 has identical language, except a slightly narrower time frame for the Tmax at 5.5 to 7.0 hours. What does Lupin's own FDA approved label say about this element. It describes the properties of Lupin's copy of Fortamet. It instructs the condition how to use it and it provides important information to physicians that are proscribing this drug. And the Federal Circuit has declared a proposed label must be truthful and accurate. The proposed label is submitted to the FDA under penalty of perjury. What does the text of Lupin's own FDA approved label say about Tmax. It says that it falls clearly within the claimed training when the product is administered with food. When Metformin hydrochloride has extended release tablet was administered with food, Tmax was increased by approximately 30 percent. And Tmax was more prolonged compared with the fasting state 6.1 versus 4.0 hours. Squarely within the claim range of 5.5 to 7.5 hours or 5.5 to 7 hours. Table one from the label further confirms the infringement. There's the second line says Tmax in hours. It's six hours. Again squarely within the range claimed in the 866 Patent.

Your Honor, we believe that is enough to prove likelihood of proving infringement. The Federal Circuit has looked at this issue and it has said, where a generic label defines a property of a generic product, such that it must meet a limitation of an asserted claim, then there will almost never be a genuine dispute of a material fact that the claim is infringed with respect to that limitation. Sure there can be exceptions, your Honor, and I'm going to address Lupin's argument that it's one of those exceptions, but the standard that's applied for this motion for a preliminary injunction is whether we're likely to establish infringement. And we believe this label with this language the way the Federal Circuit has treated such labels, ends the issue. But let's look at Lupin's arguments. Lupin struggles mightily to walk away from its own label. It first tries to argue that, oh, no, what's claimed in this patent relates to something called a steady state, as opposed to a one time use of the product. It never made this argument before. It makes it for the very first time in its opposition to this motion in a footnote and it argues that Shionogi's patent excludes the so-called steady state and applies only to a Tmax value achieved after one single dose ever taken by a patient. This argument is flawed on many levels, your Honor. First of all, it violates this Court's claim construction. Secondly, it's contrary to scientific logic and evidence, medical evidence. And it's

contrary to Lupin's own product label. First, Lupin's steady state argument contradicts the Court's Markman opinion. This Court found that single dose means the amount of drug administered to a human patient at one time. There's no indication in this Court's construction or even in Lupin's proffered arguments, Re: The Markman process about the definition of a single dose in a patient excludes the steady state. Moreover, Lupin's manufactured steady state argument contradicts the basic science. We've submitted a declaration from Doctor Lawrence Flekenstein from the University of Iowa, Department of Pharmaceutical Sciences. And Doctor Flekenstein makes the point that I think is intuitive, but we submitted it through a declaration that scientifically speaking this argument that they're making between a steady state and a single dose is scientifically irrelevant. That is steady state simply means that the peaks and valleys associated with the drug concentration are predictable and it doesn't change the body's reaction to the actual ingestion of the drug. Each time the patient takes the drug, she is taking a single dose. There's no saturation or pent up accumulation of the drug in the system, as Lupin somehow seems to be suggesting with its steady state argument. Again without support.

Finally, Lupin's newly admitted steady state argument contradicts its own FDA approved label which says nothing about any supposed distinction between a one-time only use and

an administration in a steady state. In Lupin's final effort to walk away from its own FDA approved label, it tries to suggest that it somehow had no choice but to put false information on the label. Not surprisingly, your Honor, that is simply not true. There is a provision in the CFR which allows full use to be made to labels of even generic products, even copies of drugs based on differences in pharmacokinetics such as Tmax, and, in fact, if Lupin thought there was such a difference, it had an obligation to change its label, and it didn't. Lupin's own label itself should be enough, as we say, to show that Shionogi is likely to prove infringement. But there's more. First, there's Lupin's own ANDA, the study that it submitted to the FDA in support of its approved, its product, its copy of Fortamet. And we have submitted to this Court a detailed declaration from Doctor Flekenstein detailing and translating what is contained in that submission. But in sum, your Honor, two key points come out of that declaration.

First, the study that they submitted themselves to the FDA shows that the results on the Tmax fall within the claimed, the ranges claimed in the 866 Patent if one takes into account the standard deviation that they themselves included in the study that they submitted to the FDA.

Second, that study demonstrates that Lupin's own data shows that their product has a Tmax value and profile that is virtually identical to Fortamet, and there is no dispute that

Fortamet falls within the claimed range of Tmax that's set forth in the 866 Patent. First, just looking at this standard deviation issue, and I'm not a mathematician, your Honor, but this has been explained to me that when they -- Lupin focuses on the fact that this study shows an arithmetic mean time of 10.3 for the Tmax. That's true. But the study also shows S.D., a standard deviation of 3.2. Standard deviation means if one were to run the study again, there's a 95 percent chance that the value will fall within the range of two standard deviations. So that means you apply that to the facts of this study, that means that if Lupin's ANDA study were run again, one would expect 30 of 32 subjects, that's 95 percent to exhibit a Tmax of between 3.7 hours and 16.9 hours. That is a range that squarely covers the range claimed in the 866 Patent. Also in that study they show a graph that shows the Tmax of their copying of Fortamet and Fortamet. And if we can go to the next slide, it highlights the curve that's Fortamet and then the next one highlights the curve that is their copy of Fortamet. It shows that the Tmax value for those two products is virtually identical.

Now it is true that the Tmax value in these -- in this chart is higher than what is claimed. But there is no dispute in this case that Fortamet falls within and covers the claimed change range of the 866 Patent. So what is the explanation for the fact that Lupin's study shows that both Fortamet and

its own product while having virtually identical Tmax profiles are both, have a higher Tmax value range. Doctor Flekenstein has explained in his declaration. You can go back. There's a number of factors that Lupin -- where Lupin deviated from the
01:07 studies that underlie the 866 Patent, all of which will likely increase the Tmax values for both Fortamet and its own copy of Fortamet. It gave glucose after breakfast. There was an afternoon meal. There are a high number of withdrawals from the, from the study. The salient point, though, is that both
01:08 Fortamet and Lupin's copy of Fortamet acted virtually identical when it came to the Tmax value and that leads to the opinion of Doctor Flekenstein. Therefore, it is his opinion that the flaws were remedied and Lupin conducted its test in a manner substantially similar to the tests supporting the 866
01:08 Patent. The products would not only behave similarly, which we don't dispute, but also fall within the 5.5 to 7.5 hour range described in the 866 Patent.

Finally, Lupin tries to walk away from its own FDA approved label, based on a study that it did not submit to the
01:08 FDA. Lupin provided one study to this Court that it says proves that it is likely to show non-infringement based on the study of ten patients. But this study's methodology is fundamentally flawed and its results are scientifically invalid. The study cannot be reproduced or verified. It
01:09 cannot be properly compared to the studies underlying the 866

Patent. The results, therefore, are highly questionable. But Lupin did not submit this flawed study as part of its ANDA submission, and there's a reason it didn't submit this study as part of its ANDA submission. If this study violates the
01:09 FDA guidelines on how these tests are to be conducted in a number of key ways. It doesn't have enough subject. They gave the subjects many more calories in a different mix of food, all of which has a great impact on the Tmax values that results. The study also had a number -- it lacked certain
01:10 basic information, and we've listed them all in our brief and in Doctor Flekenstein's declaration.

In sum, these flaws do not allow one to reproduce or verify the results. You can't compare the study results to other studies which leads to the a questionable result on the
01:10 Tmax value itself. Lupin tries to downplay the significance of these flaws, but we would ask the question, if these -- if this study was scientifically valid, why didn't they submit it to the FDA. Maybe if we can skip to slide 52.

Another point to make about these two slides that have
01:10 been performed by Lupin. One that they did submit to the FDA on and one that they chose to withhold from the FDA. The results that came from these two studies are very different. The one that they submitted had a Tmax of 10.3 hours plus or minus 3.3 hours. The study that they didn't submit to the FDA
01:11 produced a Tmax of 12.8 hours plus or minus 1.7 hours. And

that's the cite, of course, on which Lupin tries to rely for its argument it isn't likely to prove non-infringement. But these values vary so greatly by nearly 25 and 50 percent, that they are scientifically useless. Doctor Flekenstein offers
01:11 the opinion that in making the comparison of these two tests is scientifically difficult, if not impossible. As such I cannot with any certainty opine as to why the test results are so divergent. However, it is my opinion the divergence proves that Lupin's test methodologies are fundamentally flawed and
01:11 neither test can be verified or relied upon. Thus, your Honor, we believe that Shionogi is at least likely to be able to prove infringement by a preponderance of evidence. Based first upon Lupin's own FDA approved label which is unequivocal. To the extent the Court finds that these studies
01:12 that have been performed by Lupin are at all reliable, the study that they submitted to the FDA shows that their own product would, in fact, fall between the range claimed by the 866 Patent and the one that they did not submit as we've said is unreliable. But, of course, there's a second piece to the
01:12 likelihood of success on the merits. And I now would like to turn to that and that is whether or not Lupin is going to be able to have a likelihood of demonstrating that our patent is invalid. We believe that Lupin is unlikely to prove the invalidity of our patent claims by clear and convincing
01:12 evidence. The 866 Patent is entitled to a presumption of

validity, and Lupin can only overcome that presumption by establishing invalidity through clear and convincing evidence. And Lupin relies primarily on prior art that was already considered by the Patent Office, and thus bears what the Federal Circuit has labeled an added burden.

Now, your Honor, there is some debate in the Federal Circuit about the standard that applies for establishing invalidity at the preliminary injunction stage. There are Federal Circuit cases that say the Court should consider the clear and convincing evidence standard would apply at trial. There's the more recent case, the Abbott case where they've said that the defendant merely needs to show a substantial question of invalidity. Now, while we believe that the clear and convincing evidence standard is the right standard, ultimately, that that's ultimately where the law will end up, the fact remains that Lupin's validity challenges fail under either standard.

First of all, let us address Lupin's primary argument head on. The 866 Patent is presumed valid. All of the claims in the 866 Patent, including Claim 1 and Claim 3 were allowed and issued from the Patent Office.

THE COURT: I appreciate that. What happened?

MR. BASSETT: Good question. I'll get right to that, your Honor.

THE COURT: It's not real clear to me.

MR. BASSETT: I understand. And I'll tell you, your Honor, it's not real clear, wasn't real clear to me the first time you read it through, too. But if we could turn to slide 64. We've set forth a chronology of sort of dot key events from the convoluted and long filed history. On May 21, 2003, there was an office action rejecting the claims in light of the cited prior art and the prior art and which Lupin still relies. On November 20th, there was an office interview with the examiner, and I would show you in a moment what the examiner said about that interview. But the bottom line is the examiner was convinced during that interview that the claim should be allowed over the prior art. And on December 19th he issues an Order, a Notice of Allowance, rather, that allows the claim over the prior art, including Claim 1 and Claim 3. Now --

THE COURT: What was -- you kind of apparently attempt to withdraw or modify or something Claim 1.

MR. BASSETT: No. I was just going to get to that, your Honor. As this time line shows, between November 20th and December 19th where the examiner allowed the claims over the prior art, on November 21st, Shionogi, the applicant, filed an attempt to what they call it, an attempt to cancel Claim 1, by the way, not Claim 3. Claim 3 was never touched in any of this. But in Claim 1 that was not because of prior art, it was because they had a six month deadline that expired

that day that was non-extendable. So in order to make sure that the prosecution didn't lapse or create or have any problems, they had to try to withdraw that claim. The examiner either ignored that or didn't see it and issued the claims or allowed the claim anyway after that.

Now the examiner later saw that, that filing from November 21st and issued a revised Notice of Allowance that removed Claim 1. Ultimately Claim 1 does issue. The bottom line, your Honor, is that the examiner looked at the prior art, considered whether the claim should be allowed over that prior art and it determined, yes, it should. And that's what the examiner said on December 19, 2003. The substantive reason that there's a presumption of validity for an issued patent is that the PTO is an agency that's entitled to deference where you assume that the examiner did his or her job and understood the issues. There is no doubt that substantively the examiner looked at the prior art and determined these claims should be allowed over the prior art.

THE COURT: If I were to be convinced that they made a mistake, do I have the authority to change it? Do I have the authority to change it? What authority do I have to look into this matter as to whether there's a mistake and order that they change it?

MR. BASSETT: Okay. First of all, to address that question. There is no mistake here. What the examiner did

was issued this Notice of Allowance not realizing or ignoring the attempt to cancel Claim 1 that later got corrected and then the claim was later ultimately issued because the examiner had found that that claim was allowable. There is no reason to do anything to this. The ultimate issue would be if you determine the claims were invalid, that's what the Court, you know, District Courts do all of the time. There is no mechanism to go in and correct or tinker with what happened during the patent, the filed history. But I would suggest to the Court that there is no reason to do that here. All that matters for these purposes is whether or not that claim was substantively examined by the examiner. Whether the examiner determined substantively that this claim is allowable over the prior art. And there is no doubt that he did that. There's just absolutely no doubt.

THE COURT: There's no question he did it. He allowed them, that's for sure.

MR. BASSETT: Right. And I would suggest to your Honor --

THE COURT: He or she.

MR. BASSETT: He or she. I would suggest, your Honor, that that is all that matters. And the argument that Lupin is trying to make is a mere technicality. They're trying to rip that up into something to overcome the substantive point that the examiner did, in fact, examine

these claims, looked at the prior art and determined they were allowable.

If we could turn to Slide 65. This is the Office Action from December 13th. There is no doubt the examiner 01:18 allowed all of the claims, including Claim 1 over the prior art. A fact so indisputable that Lupin's own patent law expert has acknowledged it. This allowance didn't come out of nowhere, your Honor. As I suggested there was a November 20th interview in which the applicants discussed the prior art and 01:19 convinced the examiner that this claim, these claims should be allowed. It is true that the applicants attempted to cancel Claim 1, but that was based again on a procedural issue, not based on prior art. And Claim 1 was still allowed over the prior art ultimately based on the first Notice of Allowance. 01:19 So as I said, the substantive issue is whether the claims were examined and allowed. And there is no doubt that they were. That's exactly what happened here. And Lupin's own patent law expert admits that all of the claims of the 866 Patent were issued. Our suggestion, your Honor, this Court's inquiry ends 01:19 there. There is no reason to go behind that further. The fact is substantively the examiner found these claims allowable over the prior art and that is what creates the presumption, that's what creates the entitlement of the 866 Patent to a presumption of validity just like every issued 01:20 patent. It's clear why Lupin is trying to rely on this

technicality because otherwise they know they face an insurmountable burden in overcoming the presumption of validity. They want to suggest that even though the 866 Patent issued, even though it was examined, even though the examiner found that the very prior art they're relying on doesn't invalidate the patent, that they're entitled to somehow find this Court to find they're likely to prove invalidity because there is no presumption. But there is a presumption. And when the Federal Circuit has said -- and go to claim or Slide 73. That when the prior art was before the examiner, during prosecution application, there is a particularly heavy burden in establishing invalidity. That's what Lupin is trying to avoid here. And the prior art that was relied upon by Lupin was, in fact, before the examiner.

We can go one more slide. Lupin's invalidity contentions cited a number of other prior art references for sure. But Lupin's opposition brief to this motion does not even mention those other pieces of prior art, and there's a reason. Because they're peripheral. They're cumulative. The only two prior art references that it relies on substantively are something called Timmins and Cheng. And those two pieces of prior art no doubt were before the examiner and substantively considered by the examiner.

If we could turn to Slide 79. Both of these pieces of prior art were before the examiner and were thoroughly

considered. Both appear on the front page of the 866 Patent. Timmins discussed in the text of the 866 Patent. Cheng is discussed in the text of the 866 Patent. The examiner initialed the respected entries for Timmins and Cheng showing that they had been substantively examined. The first Office Action the Patent Office rejected the claims as obvious in Cheng. Over Cheng. In the second Office Action they did it again. Then the third Office Action the Patent Office again maintained the obviousness rejection. Okay. The inventors overcame these rejections. The Patent Office then withdrew those objections and issued the 866 Patent. And I would just remind the Court that this presumption argument that Lupin has been making here to try to defeat our preliminary injunction motion, was never made in its invalidity contention. It was never raised during the Markman hearing. This is the first time they've raised it, and they're doing it because they know that if they're faced with the presumption of validity, that they cannot prevail because they're relying solely or primarily, I should say, on the prior art that Lupin -- that was already considered by the examiner and that was overcome during prosecution. As a result, your Honor, we believe Shionogi clearly has a likelihood at least of a success on the merits of proving infringement, of at least one claim of the 866 Patent that was valid. Which leads us to the issue of irreparable harm. Because Shionogi we believe is likely to

succeed on the merits of its infringement claim, that success is relevant to the irreparable harm analysis. The Federal Circuit addressed this issue very recently in the Bosch opinion which we focused on in our brief. And I think it's worth reading the language of the -- what the Federal Circuit says about what use of the presumption of irreparable harm.

Although E-Bay abolishes our general rule that an injunction normally will issue when it happens, is found to have been valid and infringed, it does not swing the pendulum in the opposite direction. In other words, even though its successful patent infringement, plaintiffs can no longer rely on presumptions or other shortcuts, it does not follow the Court should entirely ignore a fundamental nature of patents as property rights granting the owner the right to exclude.

And, your Honor, there is no doubt that Lupin's stealth launch has and will irreparably harm Shionogi. As we've established already, or discussed already, Shionogi did not delay in seeking this relief. Lupin chose Shionogi as a target for its first ever at risk launch for a reason and I will get to that in just a moment. Lupin has suffered and will suffer --

THE COURT: What difference does the reason make?

MR. BASSETT: Pardon?

THE COURT: What difference does the reason make?

MR. BASSETT: Because, your Honor, in the balance, in the balance of harms, which is part of this Court's analysis.

THE COURT: It's a self-inflicted wound.

MR. BASSETT: Okay. Fair enough. One of the points I wanted to make. So I will move on from that. This is Lupin's first at risk launch. They did it we said. They called it a stealth launch. They brought a third of the total market needs into the country in one fell swoop, and then flooded the market with those low cost copies of our client's product. As a result, Shionogi will suffer irreparable harm. And in analyzing harm, Courts have considered things like lost market share, loss of business opportunity. Loss of the work force. Loss for funding for R&D. And all of those elements are in play in this case, your Honor. As I said, we have submitted a number of declarations in support of our motion.

I'd like to direct the Court's attention, in particular, in this context to the declaration of -- from Doctor Christopher Vellturo. If you could turn to Slide 119. Doctor Vellturo is the president of Pharmacy Economic Solutions, professor of Boston University School of Management. And Mr. -- or Doctor Vellturo explains in his declaration what should be, I believe, intuitive to many people objectively looking at this situation that this launch of such a massive amount of low cost product will cause significant and irreparable harm to Shionogi. Obviously there's the lost sales. Those potentially irreparable, and we're not suggesting to the contrary. But there's also a loss

of market share, potential loss of formulary status, loss of market development funds, loss of good will, potential loss of jobs, all of which are clearly irreparable. We've also submitted a declaration from the C.O.O. of Shionogi setting forth this impact that these -- that the flooding of the market on this product could have and will likely have on Shionogi, all of which we would argue is irreparable.

THE COURT: Let me stop you for a minute. They've been selling this product for a couple of months now. Right?

MR. BASSETT: Your Honor, no. What happened was that they launched this product, we, secretly we discovered it. We filed this motion, and as part of this motion, we reached a second Standstill Agreement. That product is in the market. It's in the -- it's out there. We don't know because we didn't get discovery about exactly where it went or how much has been sold yet. But we want to stop it whatever is out there and bring it back.

THE COURT: I understand all that.

MR. BASSETT: Okay.

THE COURT: In that period of time that their product is out there, you may not know how much they sold, but you certainly know the effect on your sales, don't you?

MR. BASSETT: Yes. Our sales have dropped dramatically, your Honor.

THE COURT: How much? What's the number?

MR. MANSPEIZER: I believe we sold about three millions dollars.

MR. BASSETT: What's the percentage?

MR. MANSPEIZER: It dropped by at least a half.

01:28 MR. BASSETT: That's what I understand as well, your Honor. So we believe --

MR. MANSPEIZER: I'm sorry. And a good portion of that was filling back orders.

MR. BASSETT: Right. The sales have dropped by at 01:28 least 50 percent and perhaps more because many of the sales we've had in this last year which has been about three million dollars, represent back orders that were in the pipeline before the product came to the market.

Historically, your Honor, when a generic comes to 01:28 market, it captures somewhere in the order of 90 percent of the market plus. And that usually takes three to six months if they're continually supplying the market. We see nothing in this case that suggests the pattern is going to be any different, and, in fact, we've started to feel that impact 01:28 immediately. As I said, they flooded the market with a third of the full year supply at one time. And as the Court knows, most States have mandatory substitution laws that require prescriptions to be filled with the lower cost generic. Last year Shionogi earned net profit of nearly 57 million dollars 01:29 on Fortamet sales in 2010. That represented almost 19 percent

of its total profits for the year. And even Shionogi -- even Lupin concedes that Shionogi's loss of market share will be significant. But why aren't those losses entirely calculable? Well despite forecasts and other predictions, Shionogi's losses cannot be estimated with reliable accuracy because there are multiple unknowns still in play.

First of all, it's unknown whether Andrx is going to introduce an authorized generic which it is now contractually entitled to do in light of Lupin's at risk launch. It's also entirely unclear whether if Andrx were to launch that authorized generic, whether it would later withdraw that authorized generic from the market should the Court -- should we win this case on the merits ultimately. And it's unknown whether we can renegotiate the terms of that agreement with Andrx. Moreover, Lupin's experts, own expert admits the entry of its generic product could expand the market for an extended release Fortamet, which would allow other generics to enter the market. If that happens, then as a result, the compensation that we could get from Lupin would not compensate Shionogi for all of its losses at all because there would be other losses due to other third party sales. There is going to be, there's potentially going to be price erosion that again is a common sense, common occurrence when a low cost generic enters the market. They can charge lower prices. They don't have RD expenses. They don't have licensing fees.

Their low cost copy may force our client to make additional, offer additional discounts in order to get its product still sold. Sometimes name brand pharmaceuticals increase their price right after a generic comes to market in an attempt to try to mitigate loss sales volumes, but that's merely the stated price. They still then have to offer other discounts and other incentives in order to make the sales occur. And we may have to compete with Andrx's authorized generic. There's also the potential and the likelihood that we're going to lose our formulary position. Right now Fortamet is in a tier two formulary position and that means that third party payors assess what level of co-pay they're willing to give. Typically once the generic enters a market, the name brand pharmaceutical is moved to a position on the formulary tiers. And placement of Fortamet on a tier three level would result in a higher co-pay, further lost sales, and perhaps loss of good will with our patients who have been very dedicated and using this product for a long time. All of our -- many of our third party payor agreements are expired at the end of this year which will require that re-negotiation with the Lupin product in the market, Shionogi will be in a very bad position in negotiating with the third party payors. Again, in a way that's unpredictable, in a way that's potentially irreparable. Even if we were to ultimately prevail on the merits, once all of that has happened, the likelihood that we could then go

back to the third party payors and re-establish a higher position, a higher tier on the formulary certainly is speculative, and, frankly, we think unlikely. And we've submitted a declaration to that extent as well. There's a potential for lost jobs and lost development efforts. As I suggested, Fortamet accounted for about 18.5 percent of Shionogi's total profits in 2010. Fortamet's profits fund the Shionogi research and development efforts. At least in part. We submitted declarations to that extent. That work is based in New Jersey. And that is a primary component of Shionogi's business here in New Jersey. If we lose those profits, it's likely to hinder Shionogi's market development efforts and its ability to add new products and may lead to a loss of jobs. And again we've submitted a declaration to that extent, going to those points. This is not speculative. This is based on a very real analysis of what could happen and it's likely to happen in light of that severe cut in the profits that the company has been able to realize. Despite Lupin's unsupported conjecture to the contrary, Shionogi cannot depend on Shionogi Japan to make up for the loss of the Fortamet profits. They're two separate companies. The chief operating officer of Shionogi, Inc., which is the U. S. Company has submitted a sworn declaration saying that is not going to happen. It's very unlikely that we're ever going to get any more money from Japan to make up for this. They've established this company

in the U.S. to see if they can succeed here on its own. It's going to rise or fall based on whether or not it is a viable business in the U.S. without infusion of cash from Japan. The only party to this litigation is Shionogi, Inc., not Shionogi Japan. And the loss of the Fortamet profits may force the Japanese parent to re-access the viability of Shionogi, Inc. and may ultimately seek a different partner for U.S. activity. And again that's all in a sworn declaration that we've submitted to the Court.

There's also the potential loss and likely loss of good will. Dissatisfied customers may loose faith in Fortamet and in Shionogi and try different products altogether. This isn't just generic bashing, your Honor. The issue here about the quality control of the Lupin product is real. It's based on their own documents that show they've had severe problems getting their product to work and to be manufactured in an acceptable way. If customers buy, get a prescription for Fortamet, it goes to get filled at the pharmacy by the generic, the patient may have no idea that they've gotten a generic as opposed to a Shionogi created manufactured product. They go home. They take it. There's something wrong with it. It doesn't work well. They could blame Shionogi for that. They could blame Fortamet. They could then switch to a different product. That loss of good will is never recoverable. It is irreparable. It's unpredictable. We

don't know the extent to which that will happen. It's a very real risk based on their own document. The good will can also be damaged by the price fluctuation for a remedy that that could result from this. Obviously, consumers generally want
01:36 lower priced products. We all do. Obviously, however, there's a statutory scheme in place that understands that research and development is important and named brand pharmaceuticals need to make money to be able to have future products. Short term interest of consumers don't always jive
01:36 with those long-term interests of society and supplying of such products. However, when -- if we win in this case, Lupin's off the market. It will be almost impossible for Shionogi to re-increase its price to the levels that it was before, or if it does, it's certainly going to face some very
01:36 unhappy patients who have been paying lower prices for a year or two and they're going to lose that good will. Again, irreparable. May lose those customers. We don't know. We can't predict.

That leads to the balance of hardships, your Honor.
01:37 There is no dispute, I believe no legitimate dispute that Fortamet is more important to Shionogi's business than Lupin's generic is to Lupin. The two companies are very different in size. Lupin is ranked fifth by the number of prescriptions in the United States. In the third quarter of this year alone,
01:37 it had filled 39 million prescriptions. Shionogi by

comparison in the same time frame had 441,000. The Fortamet sales accounted for 18.5 percent of Shionogi's net profits. But for Lupin's stealth launch, Fortamet would continue to be one of Shionogi's most profitable and important products. They've lost that. The alleged harm to Lupin's own good will is unsupported by any evidence before this Court and should be given no weight. Lupin argued successfully to this Court the information regarding its own customers is irrelevant to this motion. So its argument that it may lose good will with its customers should be given no weight according to its own argument that in the absence of proof, unsupported claims and speculations of harm to good will should be disregarded. Any harm to Lupin, as your Honor suggested, is a result of its own calculated risks to launch this product prejudgment. Lupin knew its stealth launch was an at risk launch and it knew the risks when it took that step.

The Federal Circuit has considered such a balancing analysis many times. And in the Pfizer versus Tether case said: Simply put, an alleged infringer's loss of market share and customer relationships without more does not rise to the level necessary to overcome the loss of exclusivity experienced by a patent owner due to infringing conduct.

Finally, your Honor, there's the public interest. The public interest supports strong enforcement of patent rights. Courts have repeatedly held that interest outweighs that of

the public's in getting expedited access to generic drugs. The public will get access. It's a question of what time, and Courts have said that timing is not relevant, or does not outweigh.

01:39 Finally, your Honor, we do believe that a recall is necessary as we discussed earlier. Lupin has already sold at least a three or four month supply, put it into the market place. The current Standstill Agreement between the parties expires at midnight tonight, which means Lupin could launch 01:39 another set of products into the market place as early as tomorrow.

So we do believe that getting the injunction in place and having a recall to pull back whatever else is invalid hasn't been sold, but is still able to be brought back is 01:39 necessary to at least limit the irreparable harm that Shionogi is suffering.

THE COURT: What exactly is it that you seek that the Court restrain them from?

MR. BASSETT: I'm sorry.

01:40 THE COURT: What exactly is it that you seek this Court to restrain and enjoin Lupin from doing?

MR. BASSETT: From making any further sales.

THE COURT: When you say sales, not sales to the customer, not sales to you and I when we walk in the drug 01:40 store.

MR. BASSETT: No, sir. That's already -- that's not Lupin doing that directly, right.

THE COURT: So Lupin is selling to its distributors or whoever, these third party payors.

01:40 MR. BASSETT: Exactly.

THE COURT: So you want them to stop now.

MR. BASSETT: Exactly.

THE COURT: And you want them to stop shipping any more products.

01:40 MR. BASSETT: Right.

THE COURT: Now, the recall, though, involves them doing what? If I were to order a recall, what is it you want me to order them to do?

MR. BASSETT: What we would like, your Honor, is for 01:40 them to go to their customers and say send us back anything you haven't yet sold to your customers. Your Honor, I could give you a more detailed answer.

THE COURT: What level? All the way -- you want me to direct them to go all the way to the CVS drug store on the 01:41 corner by my house and say, send back that drug.

MR. BASSETT: Your Honor, we would like them to take all reasonable measures to bring back any product that is improperly in the market place. I can't answer your question in more detail because we would have given that discovery. I 01:41 don't know what product, what customers Lupin has sold this

to. I don't know where they've sold it. I don't know how many they've sold it to. We did not get that discovery. So I don't know. But the honest answer is they know, they know what they can do. If the Court should order that this product be brought back, that they take all reasonable measures to do to so, and we're happy to be reasonable, your Honor. If they say, well, we can't go to the corner CVS because that's going to be too burdensome, then that may be correct. But they certainly can go to their immediate customers. They can ask their immediate customers to go to the pharmacy distribution centers and say send back anything that's still sitting there on their shelves. This product has a two-year shelf life. There's no reason to believe that it's all gone. It's sitting there on shelves somewhere. Many of it in warehouses, in storage facilities where it could be brought back easily. If to the extent there's individual cartons sitting on a shelf in some pharmacist's -- in a small pharmacy in North Dakota, we're not trying to be unreasonable, your Honor. We understand there's going to be limits to that. But we have no way of knowing how difficult that would be because we haven't gotten that discovery yet from Lupin.

THE COURT: Why is it sufficient to your client, if I were to just order them to stop today selling anymore to their customers, because you have these -- let's assume there's a lot of this drug out in the pipe line out there. Why would

the pharmacies and the ultimate recipients of this drug, the retail sale want to continue to sell their product when they know there's not going to be any more because of my injunction?

01:42 MR. BASSETT: Because they can still sell it more cheaply, your Honor. Because State statutes require pharmacies to do that when they have such generic product available to them. In most States this isn't even a matter of choice. A pharmacist is obligated as a matter of law to fill

01:43 a prescription for Fortamet with the generic alternative if it's available. So if the pharmacist has it sitting there or if he can get it or she can get it from his or her supplier, then they're obligated to do that legally, and in most situations. So, the irreparable harm and irreparable harm

01:43 that my client is suffering, needs to be stopped by ending what we can of those ongoing sales that could occur next week, next month, a year from now because this stuff is sitting on the shelves.

THE COURT: Well sure they can sell it. But why

01:43 would Lupin want them to continue to sell it when Lupin can no longer supply it. Isn't Lupin going take a hit to its reputation? When they've got these product out there and they say, oh, I'm sorry, we can't give you any more. That's it. No more.

01:44 MR. BASSETT: You'd have to ask that question of

Lupin, your Honor.

THE COURT: What's your opinion on it?

MR. BASSETT: I will tell you, your Honor. Thank you for asking. Generics do this all the time, your Honor. This is matter of the business model of generic drug suppliers. They will often flood the market one time only with a lot of product, make whatever money they can, crater the market and then they move on to the next product. Again, I'm not trying to bash generics or their model. They serve a valuable purpose in our society. I understand that. But from my client's perspective, when you look at the impact that it has, generics have no motivation to build good will client. Certainly with their customers that -- and that is the distribution centers that buy their product, they have good relations with them and they want to maintain those arrangements. But everybody understands that sometimes generic suppliers are going to be sporadic. They're going to come in waves. Then there's not going to be generic available next month. Then it will come again later. This isn't set up for that. It distributes what comes in. And I don't believe they would suffer any loss of good will as a result of a decision to not pull back their product simply because there's not going to be more coming down the pike. Their customers are going to be happy with whatever they can get because most pharmacies make more money selling generics than they do

selling the name brand pharmaceutical. Their margin is a little higher. Most pharmacies are going to be happy to sell whatever generic they can get. They may want more. They may be disappointed they don't get a little more, but it's not going to be the same kind of issues that are faced by Shionogi if they're not going to be able to continue to supply the market.

THE COURT: Let's talk about a bond. It's mandatory if you win.

MR. BASSETT: We understand --

THE COURT: There's big numbers out there.

MR. BASSETT: Yes.

THE COURT: There's four different scenarios in this one declaration of Mr. Hoffman as to what they're going to lose if I do this.

MR. BASSETT: We understand that and would expect that we would be obligated to post a bond. We were talking about that beforehand, and I don't have a number to suggest to the Court, but I'm happy to do so. If I could have a moment to talk with my client, we will. But I understand that that issue -- that's a fair point. That's how the system works. We understand that. We believe we're entitled to that injunction. So, we will, to the extent the Court believes that a bond is appropriate and necessary, then we will be happy to discuss what we believe would be an appropriate

amount. And in light of the numbers that have been submitted by Lupin.

THE COURT: Well, if you want to take a few moments to speak to your client right now and address that issue, I'd appreciate it.

MR. BASSETT: Thank you, your Honor.

(Brief pause)

MR. BASSETT: Thank you, your Honor. I appreciate the opportunity to consult with my client.

Our sense is that an appropriate bond would be equal to approximately one year of Lupin's profit from the sale of this product. The fact is we can't put a number, a precise number on that because we don't know what Lupin's price is. We don't know what its sales have been. And we also don't know whether or not an authorized generic is going to be launched by Watson Andrx which obviously would greatly affect the price.

We would suggest, in light of all that, we would need to have a bond hearing, to ask the Court to enter a TRO, have a bond hearing early next week. Having said that to put some meat on the bones, we could think that the right number is somewhere in the 10 to 15 million dollar range based on Shionogi's experience with the sale of this product. We understand they've submitted numbers that are much higher than that. But, again, we have no basis to know -- whether how to question those more specifically at this point because we

haven't yet gotten that information from Lupin.

THE COURT: Well, not all their numbers are higher. They have a scenario D with this six million dollar numbers in it.

01:52 MR. BASSETT: Yes, that's closer to what I think we would consider appropriate, your Honor.

THE COURT: All right. Anything else you want to add?

MR. BASSETT: No.

01:53 THE COURT: Thank you.

MR. BASSETT: Not unless you have a question.

THE COURT: No more questions. Thank you. I'll hear from defense counsel.

MR. HOCHSTETLER: Your Honor, with the Court's

01:53 permission, we are go going to divide our presentation in the likelihood of success on the merits I was going to handle and Miss Jacob was going to handle the non-patent factors.

THE COURT: Fine. Thank you.

MR. HOCHSTETLER: If it please the Court, I have five

01:53 main points and two binders. If I could present the binders.

THE COURT: Thank you. The larger one is first.

MR. HOCHSTETLER: Otherwise the larger binder are the slides going to go through on likelihood of success and the smaller binder addresses the Court's question about what is it

01:54 that happened during the patent prosecution about these

claims. And I inadvertently got -- we have a table of contents and each document and I would propose to trek through the prosecution history with the Court, so the Court can see what, exactly what happened. What you're going to see happen, Judge, is that the patent attorney three times asked for all of the claims to be changed. The examiner signed off on it and only then was the patent finally allowed the second time. And so that the argument that you hear that the examiner must have decided during the interview the claims up to 7.5 would be allowable. The contemporaneous documents and the actions of the people involved are inconsistent with that position. But I would propose, unless the Court would otherwise prefer the bigger binder on likelihood of success.

THE COURT: Fine.

MR. HOCHSTELER: Because your Honor's first question of plaintiff's counsel was the Doctor Shepard study. And the Shepard study is the only study after dinner on Lupin's product. It shows the Tmax is 12 hours. That doesn't infringe. Plaintiff talks about, well, you didn't submit it to the FDA. It's not a bioequivalent study. The generic is supposed to submit all bioequivalent studies, but it's not a bioequivalent study. The -- and with respect to its reliability, slide I think it's 53 of Plaintiff's, Plaintiff's slides contrast the standard deviation of the FDA approved study and the after dinner study of Lupin's. And the standard

deviation is bigger, according to their slide on the FDA approved study than on the after dinner study. Doctor Shepard, a true expert in this field, has looked at the study and concluded it provides in the declaration that the study is, in fact, valid scientific proof that the Tmax of Lupin's product is 12 hours, and it simply does not infringe this patent.

The second point, the plaintiff then talks about the FDA submitted after breakfast study and the argument kind of goes like this. Lupin's product after breakfast they say it's like Fortamet. Therefore, after dinner it would be like Fortamet, too. And what I'm going to show you in a couple minutes, your Honor, a graph which plaintiff omitted from the presentation to you which is going to show that Lupin's product is, in fact, is a very different Tmax. Two hours longer than Fortamet. The package insert, the third point, your Honor. We cited the cases that establishes what seems like kind of the odd proposition that a generic label is not a representation. In Pliva the argument was that the representation by the generics was inaccurate. Here the plaintiff says the representation is accurate. But neither one is right because a generic does not make a representation about the accuracy of the data it has copied from the brand label. And let me give you a quick example just from our own experience. If you get a prescription, Judge, and the doctor

writes it out, he may or may not -- you're going to, you know, that you're going to go down to the CVS to fill it, but he does know, the doctor, what generic drug company your CVS pharmacy is buying from at that time. If the doctor has to worry about the label being different for each generic company, then he can't safely allow a generic substitution because he doesn't know what the label is going to say if it's going to be important. Then he would write do not substitute which is exactly what the Hatch-Waxman Act is designed to avoid. Congress wanted to encourage generic substitution.

So what this -- this whole system is set up so that the generic drug has to be shown to be just as safe and just as effective as the brand drug using the brand label. And if it is not just as safe and just as effective, it doesn't get approved. My presentation I'm going to go through the statements supporting that, but that's the fundamental proposition, and that's why --

THE COURT: Well, you're not suggesting that this labeling requirement is a mere formality, and you can have your product, your tests show that your product performs differently than the label.

MR. HOCHSTETLER: What I'm suggesting, Judge, is that the label is not a formality, but what a generic firm has to show -- maybe I should jump to, into a slide. I don't know how to jump ahead, Judge. I'm going to have to just scroll on

this.

Let me start here. I don't think there's any dispute that Lupin's label is a copy of the Fortamet label. The names are changed.

02:00 THE COURT: Right.

MR. HOCHSTETLER: And, in fact, just kind of make an interesting point. It's changed so completely that the tense didn't even change. Fortamet was administered by Metformin. Hydrochloride was administered. It is the same data and, of
02:00 course, the FDA knows that. And the FDA gets test data from Lupin on a variety of parameters particularly Cmax and AUC. And the reason they do that is because under the statute, the generic has several obligations. The number one obligation is the active ingredient has to be exactly the same. Okay. Has
02:01 to be Metformin. And that, in fact, becomes the distinction between the Abbott case they rely on so much, Judge. In the Abbott case the generics that we represent that that's the active, the same active ingredient. And the Abbott Court held them to it. But a generic goes also, only has to show the
02:01 drug is bioequivalent and the statute is explicit and it is clear that it's not supposed to be a copy. It's only supposed to be bioequivalent.

THE COURT: It doesn't say it's not supposed to be. It says it can be.

02:02 MR. HOCHSTETLER: Okay. Right. Okay. But as a

result though, the generic routinely will have different Cmax and AUC values. If plaintiff were correct that the generic label was supposed to contain exactly the same Cmax and AUC and Tmax and other pharmacokinetic parameters that were shown in the ANDA, the generics provided, then all of the ANDA labels would be different within the brand. And that's not what happened. Instead what happens is the FDA looks to see whether the differences matter. If the differences matter, then the generic drug does not get approved. If the label differences do not matter, then the generic drug is approved and it's approved with the brand's label.

THE COURT: But the label. And I know you have to, the generic has to use the same label. But isn't that because the public has a right to expect that the generic drug will perform exactly as the label indicates it will?

MR. HOCHSTETLER: No.

THE COURT: No?

MR. HOCHSTETLER: The label, it's directed to medical professionals. And using my CVS example before. It's the public or the doctor is entitled to presume that any labeling difference, any differences between the actual pharmacokinetics of the generic and the brands, are not important. Because the drug is still bioequivalent. So --

THE COURT: Right. I understand that.

MR. HOCHSTETLER: Okay. All right. So in this case

where they're focusing on the package insert of Lupin's product, the AUC of Lupin's product is not exactly 26,811. It's not exactly a Cmax or whatever it was and the Tmax is not the same. But the FDA has determined that those differences between the performance and the brand label don't matter. And that determination is entitled to deference.

THE COURT: Don't you have the ability to ask the FDA to permit you to change your label?

MR. HOCHSTETLER: Lupin --

THE COURT: In reality?

MR. HOCHSTETLER: Lupin believes the answer to that is no, Your Honor. And again the, the Federal Circuit in the Abbott case dropped a footnote that said, that Abbott -- that the generic could have filed what's called a suitability petition to change the label. But we've cited it in the Federal Register portion and it's included in your binder, your Honor, where the FDA says a suitability petition is not appropriate for such labeling changes. So it's not at all clear, your Honor, that, in fact, Lupin could change the label and perhaps more importantly, though, we know that the FDA had in front of them data that was inconsistent with the package insert data and approved Lupin's products regardless reflecting an administrative determination that the differences were not important for safety.

THE COURT: I understand that. But the FDA didn't

say, okay, so you don't have to worry about your labeling. Rights. You can use the same label, even though it's different. They never told you that. They told you the drug you can sell the drug because differences aren't substantial enough. But they never commented on your label, did they?

MR. HOCHSTETLER: Oh, no, no, your Honor. I'm sorry. Yes. And you have to submit side by side. That one --

THE COURT: Right. Do you have to submit the same label?

MR. HOCHSTETLER: But the FDA has to approve it, your Honor. The whole point --

THE COURT: Why would they not approve it if it's exactly the same?

MR. HOCHSTETLER: Why would they not approve it. I'm sorry?

THE COURT: Why wouldn't they approve it if you submitted the exact same label as the patented drug.

MR. HOCHSTETLER: Well, in fact, the statute wants the label to be the same.

THE COURT: Exactly.

MR. HOCHSTETLER: For the reason, though, that I described because of the differences in this case between the pharmacokinetics, between the performance of the generic drug and the brand drug don't matter. So, that's why when Lupin includes the Fortamet data in their package insert, it's not a

representation if the AUC is exactly 26,811 or that the Tmax is six hours. All it is is the representation that this is the data that it was provided in the Fortamet label.

THE COURT: But don't doctors assume that it is the same?

MR. HOCHSTETLER: The doctors would assume that it wouldn't matter. The differences wouldn't matter. And, in fact, we submitted the declaration of Doctor Shepard who said for this product it does not matter.

THE COURT: I'm not challenging the FDA's approval of the sale of your generic at all. That's not the issue here. The issue is what effect does your label have on your argument that you raise a substantial question here.

MR. HOCHSTETLER: And my short answer is, your Honor, is that the label is, at most, some evidence but is outweighed by the other evidence that is properly understood is labeled, is not an admission that the Tmax is six hours. That's -- and this is a little later in the presentation, but they refer to the Research Foundation case where is one where the label was viewed as an admission of infringement. There was a trial held in that case, your Honor. And the District Judge then taking all the evidence said that his reliance on the label did not withstand scrutiny. And this is before Pliva. And Pliva, your Honor, I would respectfully suggest changes, changes the law because the Supreme Court said that the duty

of a generic is to copy the brand label. It's the job of the brand company to make sure that the label is accurate.

With respect to, if I could switch to validity now and then I'll -- unless the Court would --

02:08 THE COURT: No. That's fine. Please do. Of course, you're dealing here with a presumption of validity of the PPO.

MR. HOCHSTETLER: Right. I'm going to address at some -- if I may, let me continue with the infringement and then I will go through validity, if that's okay.

02:09 All right. Sometimes I wish we still had the Elmo. I'm sorry, your Honor. I should have brought my teenagers. Very good.

All right. In the prosecution of the patent, a distinction was made between dinner and breakfast. The prior

02:10 art change reference discloses the same structure by, in that it provided a Tmax right in this range of five and a half to seven and a half, but only after breakfast. So the claims were changed to limit them to dinner. And this is an excerpt from the prosecution history. Particularly just the examiner

02:10 had asked what's the difference between these two, the prior art and the invention. And the answer was we have two laser drilled holes. And that's something that, the underlining there is not underlining. It's actually in the prosecution history. And your Honor's Markman opinion touched on this

02:10 that the parties all agree that after dinner is when this

patent invention is really supposed to work. So the limitation of dinner is not some technicality, it's actually fundamental, which is why because these claims are expressly limited to dinner, and there's one study on the Lupin product following dinner. That's the Doctor Shepard reviewed study. That study is powerful evidence on non-infringement and certainly satisfies Lupin's burden of showing that they have a substantial case of non-infringement.

The plaintiff has relied on the breakfast study that was submitted to the FDA. And in their brief they say that Lupin's product of Fortamet are nearly identical. They stood up here before you and essentially said the same thing, there's a problem, though. Judge, they presented to you, but -- and I'd ask you to look at slide seven. If you could clear it up. There are two figures on the page that they drew their graph from. They only gave you one. They gave you the one with the logarithm scale. There's also a linear scale. And it -- your Honor, I don't know whether you covered logarithms when you were in school, but you may recall if you did, that the number 1000 could be expressed as ten times ten times ten or 10 to the third which is a log three. One hundred would be ten times ten or ten squared. Log two, ten, log one and by convention one is considered to be ten to the zero and thus log zero. A log scale is applied here means that for each factor of ten on this graph, they move an equal distance by

the inch or so. The Richter scale, your Honor, is an example of a logarithmic scale where if you have a Richter scale earthquake of eight, it's actually ten times stronger than an earthquake with a Richter measurement of seven.

02:13 Now, here's -- and we colorized it. Here's the graph with a log scale that they're pointing to and the time, it's going to be same on both. And the vertical access is the mean concentration. It's in the blood. All right? But look at what's going on. They don't start at zero. You start at one

02:13 because this is a log scale. And the same distance as you go from one to ten, this is anagrams from the liter, and it's the same distance as when you go from ten to a hundred anagrams from the liter and then the same distance when you go from one hundred to a thousand anagrams.

02:14 Now the effect of this is to squash all the data at the top which is where the rubber meets the road. The issue is Tmax. Now, remember I said this was one of two graphs on the same page. The other graph, it's the same data. And we've added the other. We've added the color. You can see that the

02:14 Fortamet has a Tmax earlier than the Lupin. It's two hour's difference. This is the data that we have and actually included that in binder, Judge. And again here, here the scale is not the long scale. This is the linear scale. So the same distance as you go from zero to 100 anagrams, 100 to

02:14 200. Same distance, 200, 300, 400. As a result you're not

squashing everything at the top where the maximum levels are. The maximum levels for both products are right about 880 anagrams a millimeter, give or take. So the effect of their presentation is to make it look as if the Fortamet and Lupin products are as they put it, their expert said, almost an identical Tmax. This is the great Doctor Flekenstein who has all of these wonderful credentials, but he then says based on the long scale that that's -- when, in fact, the graph, the Tmax, the maximum plasma level for Fortamet is two hours earlier than for Lupin's product. And, again, this is the back of slide 20, your Honor. We have the data that we referred to the Lupin, pages 94 and 95. The data, actual data that is depicted 2396, and these two graphs are on Lupin production Document 2396.

So, we respectfully submit that the linear scale, the proper scale disproves Doctor Flekenstein's assertion that the two products have almost an identical Tmax. And it's the same that Doctor Flekenstein who turns around and has all of these criticisms of Lupin's after dinner study. The study that has a better standard deviation than the study that the FDA approved. And Doctor Shepard has concluded, looking at the data and the study that the after dinner study of Lupin, the only after dinner study in the record of Lupin's product shows scientifically, in a scientifically valid manner, that Lupin's product does not infringe. The Tmax is way outside by a Tmax

of 12. And there is no contrary evidence on the part of plaintiff.

I don't propose, unless the Court would like to hear them, to go through all of the criticisms that Doctor Flekenstein offers, but --

THE COURT: No. Thank you.

MR. HOCHSTETLER: All right. Some of them are just silly. The question is how could you use glucose both in Lupin's after breakfast study that went to the FDA and also in the after dinner study. And FDA specifies you use glucose. It's right in the recommendations which really isn't too surprising because this is a drug that is supposed to lower glucose levels in the blood. You're giving it to healthy people. You want to make sure you're not hurting people by -- okay. So the conclusion on the non-infringement is, the only data that we have is the Tmax after dinner of Lupin's product is 12 and a head to head comparison, the one that plaintiff wants to rely on, the after breakfast study shows that Lupin's product is two hours longer in terms of Tmax. And that's --

Now, let's talk about the package insert. Three elements of this. Judge, wrong task, wrong product. And also I would like to talk more about the case law involving Pliva. First on the wrong product. I think your Honor already has acknowledged, I believe that you recognize the data that's reported in Lupin's package inserts is the data on the

Fortamet product, not the Lupin product. Right?

THE COURT: Yeah.

MR. HOCHSTETLER: Okay. Okay. Right. So let me talk about the -- this I covered them and then the table describes the tests therefore conducted were steady state after four weeks. So that's what the package insert says. And so the issue is whether as plaintiff posited, that's an admission that the claim limitation that requires a Tmax of five and a half to seven and a half which, to occur after only a single dose is given.

Now, I do not presume obviously to tell the Court what it was intending to rule when it construed single dose. The Court may recall that Lupin joined plaintiff in the proposed definition of single dose and the plaintiff summed up what single dose meant. That it was a total amount of drug taken at one time, is essentially what Plaintiff's position is. Now Mylan's counsel raised the question about whether this would encompass in effect drug held over in the body for a while. And the Court had an exchange that as we were sitting there, we understood in view of the Court's ruling to seem to address Mylan's concern that the claim term is going to be limited to a total amount of drug taken at one time and not to the situation that was worrying Mylan's counsel where we keep giving the drug after some period of weeks and then a steady state developed. So that's what I would take Lupin understood

your Honor ruled that obviously your Honor knows what it intended. I would only say if it was the Court's intention to adopt what plaintiff is arguing now, which is that a single dose could encompass multiple doses, then the Court has been led into error because intrinsic evidence is directly contrary to that. And with that proposition, then the package insert statement about a Tmax of 6.1 is not an admission of infringement because it is not data on a single dose.

Let me, if I could talk a bit about Pliva. Rendered in June after the cases that the plaintiff's relying upon and it's different facts, but the facts actually helped prove our point. When you look at the District Court cases from which the Pliva arose, the allegations were very similar to what you have here. The one plaintiff was saying that the risk ratio in the generic label is not accurate. Another District Court had said it's a generic duty to make sure its label is accurate. And the Supreme Court adhered to the FDA rules that said the generic could not change the label, and reversed those views.

Now, the subject matter of Pliva was a tarta dyskinesia. It's a terrible side effect, Judge. It's not -- years ago we had an image of schizophrenics who would -- you know, uncontrollable emotions and you know twist their heads and things like that. And it was believed that was due to schizophrenia. It turned out that it was actually a side

effect of schizophrenia and drugs. And what that side effect was called tarta-dyskinesia. And it's irreversible. It's a terrible thing. My point about going into that is that plaintiff's Doctor Flekenstein again says that the Tmax is really important. Our Doctor Shepard says Tmax difference, differences in label for a product like this, an extended release product it's designed to go all day. It says the Tmax difference doesn't make any, it doesn't make any difference. But almost certainly though you'd have to say the tarta-dyskinesia is a more serious concern and it be more important to get it right than the Tmax differences. And so in Pliva the generic did not have an obligation to make sure Pliva is accurate, accurate then there was no obligation on Lupin here regarding the Tmax. Let's assume for a moment that plaintiff is right. Let's assume for the moment that, in fact, Tmax is really, really important. Then the FDA has taken the position and we have forwarded here, and again the patron Federal Register included in the binder that says if the generic drug presents a different safety issue for which a labeling change would be necessary, we're not going to approve the drug. That's not what the generic approval process is all about. The whole idea of the FDA is the generic drug is supposed to be just as safe and just as effective with the brand label. And if it's not, then the drug doesn't get approved. And difference is due to the FDA determining in

this case that the, that the parameters are close enough. That the label can be safely used. And deference is also on the FDA's construction of its own regulation that limits greatly the extent of the stated -- allows only a narrow
02:25 variation for a manufacturer, generic manufacture to vary from the brand label. I have to smile a little bit when -- in a footnote that the plaintiff called a reading of Pliva bizarre. Because the Pliva Court actually in the majority opinion actually defended itself and said it's not our job to, you
02:25 know, to decide whether the statutory scheme is even bizarre. And here the FDA regulations are furthering the statutory purpose to generic substitution. And an integral part of that is to have the generic label be the same as the brand label.

Now I'm starting to repeat myself. I touched on this
02:26 before. Just to remind the Court real quickly because it ties into the Abbott case. The generic has to show that the active ingredient is the same. But that the tablet itself is only bioequivalent. And generic firms consistently, Judge, use the brand label. And don't tinker with their package insert to
02:26 reflect little changes in the Cmax and other factors. This is just the normal way the generics do it. And as to Lupin, that's the way Lupin always does it. And as the plaintiff's counsel pointed out, they're doing a lot of prescriptions here in the United States and every one of those are drugs that the
02:27 FDA has approved and the labeling Lupin uses was approved.

And here again this is just a what I said the before by the FDA that if the drug is not as safe and effective with the brand label, then it doesn't get approved. We're not going to approve a generic drug and then tinker with the label. We need to do that for safety.

Okay. The Abbott case. If I could start with that. Abbott involved a representation by the generic that its active ingredient was the same. The Abbott Court held them to it. Although interesting the Abbott Court also considered other evidence. But again going back to the statutory requirements. Lupin here had an obligation to say that the active ingredient wasn't the same. I mean if the issue was whether our product contained Metformin, then your Honor would be entitled under Abbott to say you said your product, your active ingredient is Metformin. I will hold you to that. But now then it comes to bioequivalent. It's not a representation that the Lupin drug is just the same as the Fortamet drug.

THE COURT: The representation is that it performs the same.

MR. HOCHSTETLER: It performs -- no. It's a representation that it performs --

THE COURT: That's what it says.

MR. HOCHSTETLER: Substantially?

THE COURT: It doesn't say that. It says the same. It is the same.

MR. HOCHSTETLER: I don't believe --

THE COURT: It says what it says. It says exactly what the other label says.

MR. HOCHSTETLER: Yes, Your Honor.

02:29 THE COURT: It doesn't say or substantially like this other drug. It says we are this other drug.

MR. HOCHSTETLER: Your Honor, I respectfully suggest that medical professionals understand that the, that the generic drug, that the parameters will vary and can vary

02:29 because the drugs are only bioequivalent. They're not identical.

The other two cases that they cited Rambacy, basically the understanding that the change is being effective regulation. The Pliva case address would permit the generic

02:29 to correct an inaccurate statement. And Pliva said otherwise that wasn't an option. And here in a research foundation case, the Court looked at the label. The generic's counsel had represented that everything in the label was accurate. And the Court still though considered evidence outside the

02:30 label. And then when the Court had a trial, it then, that its reliance on the label at the preliminary injunction stage did not withstand scrutiny, because looking at all the evidence there was not infringement.

Summary of the non-infringement, your Honor. The only

02:30 data on Lupin's product, a test of Lupin's product shows

non-infringement, Lupin's product performs differently than Fortamet. And that's what the data shows, and it's a matter of facts because it's -- it was not a single dose test reported in the package insert. And also as a matter of law, the package insert is not a representation that Lupin's Tmax after dinner in a single dose is six hours.

Your Honor, I would continue on validity or what's your pleasure?

THE COURT: Let's go to irreparable harm, if you would. What kinds of damages that the plaintiff claims from the alleged infringement.

MR. HOCHSTETLER: Your Honor, Miss Jacob will take over for me.

THE COURT: All right.

MS. JACOB: Your Honor, I also have handouts.

THE COURT: Oh, good.

MS. JACOB: If I may approach?

THE COURT: Sure. Thanks.

MS. JACOB: Your Honor, this structure that has the slide bound separately and then the documents that are referred to in the slides are in the binders.

THE COURT: Thank you.

MS. JACOB: Your Honor, my name is Beth Jacob. I'm appearing on behalf of the Lupin defendants to discuss the second of what's really the second, third and fourth of the

preliminary injunction factors, which is, the first one is irreparable injury is whether Shionogi has shown that Lupin causes immediate irreparable injury and that that injury will be prevented if Lupin is enjoined.

02:33 THE COURT: Well, Lupin -- I mean Shionogi claims price erosion, loss of market share, reputational injury. Aren't they typically things that are found to be irreparable harm?

MS. JACOB: Your Honor, they are things that 02:33 sometimes are found, sometimes are not found, depending on the facts of the case. They cited cases. We, yes, cited cases where the Courts found -- I mean, for example, the Altona case which we cited was a Federal Circuit affirmed of a District Court which rejected all of those claims as showing 02:34 irreparable harm in that case. There are other cases that we cited which point out that if every time someone had an R&D department and they claim they were going to lose assets that they could use to support the R&D, it would mean that the preliminary injunction must routinely be granted, if not 02:34 always be granted every time you have a generic brand or any sort of patent infringement. And the fact of the matter is that preliminary injunctions are not a routine remedy. They are an extraordinary remedy because they distort in the normal way of a case proceeding and they're asking the Court to take 02:34 a drastic step based solely on only preliminary and not fully

flushed out information. So, yes, when a showing has been made in some circumstances you can find irreparable injury, obviously injunctions are granted from time-to-time. But it's not the norm. It's not in every case and it's not enough for the plaintiff to say, oh, Judge, loss of jobs, without more, and have the Court then enjoin this matter. I'm sort of jumping. But, for example, all they have said is lost jobs, and then they say in New Jersey. And this is an Indian company. So somehow that should be relevant to the court. In the cases where that has been a fact, that has been considered, there has been evidence that exactly why the jobs will be lost. Sometimes how many would be lost. And there is some relation between the harm and the jobs.

Here as I will go through, Shionogi doesn't have employees working on Fortamet. They stopped promoting this product in August 2010. They don't manufacture it. Andrx manufactures it. And I mean maybe they're saying there's one person who does the accounting. I don't know. But there are no jobs that are tied to this particular product and the size of this market. And they have not shown any evidence, any facts. They've not given any explanation of why they are saying that this would be a loss of jobs, other than they want us to cite this because it has been a factor that some cases have considered.

THE COURT: Do you agree that they're going to lose

market share?

MS. JACOB: Yes, I think that's -- I mean obviously because if they didn't, then Lupin would not be selling the product. But a loss of market share, the loss of sales as their own expert conceded is as they conceded this morning, that is reparable. A number can be put on that.

THE COURT: How about the price of erosion. Do you agree that they face that because of your competition?

MS. JACOB: Well, your Honor, I think it's slide -- it's document 20 or 21 in the binder. But it turns out that what Shionogi has done over the course of its history has been to steadily raise the prices on its product. There was one in April 2011, and then there was another in -- on November 8th, I believe, 2011 where Shionogi, after Lupin was on the market after the generic competition. It's tab 20, your Honor. We have a summary chart and then we have the printout of the public data and Lupin -- I'm sorry, Shionogi raised the price of a thousand milligrams at 25 percent on November 8th. And it raised its price of 500 milligrams 62 percent on November 8th.

THE COURT: But that's really typical in this industry when a generic is going to come on the market, isn't it?

MS. JACOB: Well, Your Honor, I know that Mr. Bassett said that but he said that without any support. And I don't

think it is typical that they have argued in their papers that what's going to happen is their price will be eroded and they will have to decrease their price in response to Lupin's launch. Lupin's expert said, well, you know, that's not always the case. Sometimes the brands raise their price. That they'll have a smaller market and they're going to get more money. And sometimes it doesn't affect the price. Their response was, in this case, our price will be eroded and we will have to lower it. And shortly after they filed its papers, they raised their price. So there's no indication, and they have done that steadily over the years. So there's no indication that this particular market and this situation, that there's going to be any price erosion. There will be a loss of market share, but it appears that they will continue their practice of raising prices, which also relates to their claim that they have price sensitive customers, because what they have shown over their history is that their customers, I assume they believe will continue to make purchases of their product despite the steady increase in price and despite the fact that they are already competing in a generic-size market. This was our summary that was quantifiable because even if they do set their harms, if those harms can get a dollar figure, and an estimate or a prediction of a dollar figure is enough, as I'm sure the Court is well aware, there are many cases when damages are awarded looking to the future. The

fact that the future can't be a hundred percent definitely determined doesn't mean that you can't determine damages. It also shows that Shionogi gave up on the Fortamet market before, long before Lupin launched. This is not a market or a product which is significant to Shionogi, except for, perhaps, in this courtroom. And I think that is, that is important. It goes to the balance of hardships. But it also goes to the irreparability of the harm.

THE COURT: How about the loss of good will?

MS. JACOB: Your Honor, they had two reasons for asserted loss of good will. One was they're going to have to raise prices. I think the documents that I have presented to the Court and the record shows is that they raise prices all the time. They raised prices not even a month ago. That doesn't seem to be a good will issue for Shionogi. The second is the supposed inferiority of Lupin's products. They say that people are going to buy Lupin's products and somehow it won't be as good and they'll hate Shionogi for that. That argument is a little inconsistent because there they're assuming that people will not know that it's Lupin's product. And in their other good will aspect they assume people will know that it's Shionogi who is raising their prices and they can't have the generic anymore. But in any event, if you read the e-mails, aside from some colorful language indicating that Lupin, like many other companies, seem to have a little bit of

interoffice feuding going on.

THE COURT: When will they learn to put these things --

MS. JACOB: And they use e-mails that they shouldn't use. But leaving that aside, your honor. What happened there is in one day they had an issue with one of the parameters of coating, the amount of water included that you take all the colorful language away, Doctor Kilconey went in, identified what the issue was, which was as it says in the e-mail, the parts that they didn't quote to the Court, and I don't have it right in front of me, but in effect he said it was a question of I believe the patent was not quite close enough. It was a little too far and it was in this rainy season. They solved it easily in a day. They were able, therefore, to go forward, coat the tablets, meet the parameters and launch their product. It is not as it Lupin is out there manufacturing product without any oversight. They have FDA's oversight. They have quality parameters and quality control. When the product was shipped to the United States, they have quality assurance documents which goes through all these parameters and represents based on testing of the data that they meet the parameters. So the suggestion that there is an issue because the generic product, the Lupin's product somehow is not going to perform properly, or somehow is not going to perform as well as, at least as well as the brand, has no basis and

really is not a consideration at all.

The good will issue here is not to be affected what people take and those people who have taken it for the last two months. There has been no issue or no concern or no complaint either by the regulators or by the sales people or by the doctors or by the patients that somehow Lupin's Metformin product is not performing as expected or as well. So I think that's just a false issue. I think it's a fun e-mail for plaintiffs to see. But otherwise, it really doesn't show anything, other than people losing their temper a little bit perhaps in the rainy season in India.

THE COURT: Are you going to talk about recall? Is that part of your presentation?

MS. JACOB: Yes. I'm going to go without slides, your Honor, because I'm not able to jump through the slides quite as adeptly as I should. But the recall slide. I thought it would be easier. But recall basically is slide 28, your Honor, if it matters. But recall is an unusual, very unusual remedy. The suggestion in Plaintiff's papers that courts just routinely in these situations grant recalls is not really the case. They have managed to find, I think I found two cases or three cases. I wanted to mention a few of them. One is the Plavix case which has been discussed by the experts at some length. Doesn't show the market will bounce back or how fast it will bounce back. But Plavix is a case where

plaintiff say, see, generics flooded the market. There perhaps they did, unlike Lupin which put three months onto the market. They said the Apotex in that case flooded according to the case, the decision was nine months I believe. Recall
02:44 was requested in that case. It was not given. And the Cyclobenzaprine case. But in that case, that was after trial. Judge Robinson of the District of Delaware granted a recall. Two days later, I don't remember what the Order was issued on the weekend or the day after, the Federal Circuit stayed the
02:45 recall. They let the rest of it stay in place. Left the injunction in place. They stayed the recall. That's not a case where a recall was granted, or was granted and was upheld by the Federal Circuit. So we're left with two cases. The Ortho McNeil case. In that one, the case said the product had
02:45 not been sold. It hadn't gone into the distribution chain. So that a recall was not really the sort of burden on Teva that it would be perhaps on Lupin. In that case also I know plaintiff said we didn't delay. We did it I think as expeditiously as possible. I would like to get to that. But
02:45 if you look at the chronology on the Ortho McNeil case. On June 29th, Teva got final approval and shipped its product to its distributor. On July 1st, a couple days later the preliminary injunction application was brought to the Court. On July 15th pursuant to an agreement, I don't think there was
02:46 a formal standstill in that case, but there was an agreement

between the parties that Teva wouldn't do more than let its product sit with the distributor. The case was argued and not even a week later it was decided. So that was the case where the argument of the brand company that it needed a recall, they had first of all very specific information about how this would affect their operations, about how it would affect the job hiring. But it also went very rapidly before the product had gotten out in the market, which supported the brand's position that this was a critical product to them and the recall was going to be a problem.

In the Abbott case, there's really very little discussion about recall in that case. They just say at the end they're going to grant the request for a recall for the bond. That case the Court had found that the product was infringed. I believe, I may be wrong, I think that one was after a summary judgment ruling. But that's it. Let's look at here where the recall was warranted in this particular case. When this even more extraordinary, exceptional remedy, leaving aside the burdensomeness, whether it would be effective because a product is out in the market. I mean they keep on -- they like to use the word flooded the market and that's not really what happened here.

THE COURT: I don't know what happened here. I have no data to reach any conclusion about what's in the market, other than your product is in the market to some extent.

MS. JACOB: Well, your Honor, the information that's in the record is that Lupin launched about three months worth of the product. And that I guess there isn't much more about how it is going through the distribution chain. There is no
02:48 evidence in the record except for what we had just put in that the price increases about what the effect has been on Shionogi. We've tried to find it, but there's a time lag apparently between that.

THE COURT: And that's why I asked the question as to
02:48 what the effect has been and I got an answer from counsel.

MS. JACOB: But, your Honor, we have no opportunity to review that or go behind that answer. Going back to what saying a little earlier is that for Shionogi this is a declining market and that's another reason why recall really
02:48 would not be, would not be appropriate. There's also no evidence that any future harm would be forestalled by a recall, or that I would think the Court was questioning about, that if the product is there or being sold, I don't think we have a question about inferior product. If there is a price
02:49 issue, Shionogi has already raised its prices dramatically in response to the generic launch. Once the product is sold and then if the market then at that point does not have a generic, Lupin's generic in it, the prices will do what they will do and the product will or will not be available, which is
02:49 another issue which hasn't been discussed yet. That Shionogi

attacks Lupin for having a manufacturing issue that would solve in a day. Andrx Watson had a manufacturing issue in which they said they haven't told us anything about it except that it took them one year for the 500 milligram product to
02:49 figure out how to resolve it and get that product back on the market, which either is because it's something extremely serious or it's another indication that this is just not a very important product for the plaintiff, and that they saw no compulsion to resolve this and get this on the market. The
02:50 500 milligram is back ordered. The customers in the market had no idea what the issue was. They thought it was just not being provided.

Another point I just lost for a second, your Honor. But that also is an issue, the declining market that they have
02:50 withdrawn their support for. They are raising prices. They're not giving the product. They're not supporting the product. There's a public interest in having the product if there is, then perhaps you actually do some generic participation to make sure the product is provided and to make
02:50 sure that the market it exists and continues to exist which is another, yet another issue on where the hardships lie.

THE COURT: Isn't it also a very strong public interest in enforcing patents? I mean I thought patents are granted pursuant to the Constitution of the United States.

02:50 MS. JACOB: There's a strong interest in enforcing

patents, your Honor, as the Patent Office issues them. So here I don't think we have the type of strong interest in enforcing a patent that you would have in a case where there wasn't the irregularity you have here where this plaintiff didn't bother to correct the patent. The patent that is printed that is before the Court is not the patent that the patent examiner approved and issued. And what that means for infringement or invalidity, what it does mean is that this isn't the patent that the Constitution talks about as having a strong public interest. There is a countervailing public interest, and that is --

THE COURT: I'm sorry. You have to back up a minute. You're saying the patent at issue in this case is not the one issued by the Patent Office? They're relying on was not issued by the Patent Office?

MS. JACOB: The patent that they're relying on was printed up by a printer's error which printed not the claims which were ultimately allowed, but the claims that were allowed by mistake. And Mr. Hochstetler knows this better than I do. But my understanding is that we have the claims that were allowed by mistake in December. They were then, the prosecuting attorney went back to the Patent Office to say that this was a mistake. Please issue the correct one. The Patent Examiner said yes, that's right. Here are the correct ones. Here are the claims that should issue. And what was

printed up was the ones that were originally allowed, not the ones that were ultimately allowed.

So it's not the patent that the Patent Examiner intended. And, therefore, we don't have the type of very strong public interest in enforcing the patent rights which are balanced by the strong interests in having low price generic drugs available on the market, especially in a case as here where the market is not being supported by Shionogi. So without Lupin's presence, we didn't have a 500 milligram product because Shionogi and Watson had just abandoned that market for a year. There are also arguments and I can go through it or ask the Court to look at the slides and look at the backup documents and read the briefs. But this market has been in decline. Shionogi itself predicted a 25 percent decline.

THE COURT: No, I agree with that.

MS. JACOB: So it's not the sort of situation that is present in the cases or would suggest that there's not a public interest that's in the negative. It is a situation where the public interest would be more strongly in favor in having the generic on the market than otherwise, and in some other cases.

One other point on that in terms of preventing harm. Since Lupin launched, Watson's intent the right to launch the generic and that's clear in the license agreement which is in

the materials that I've submitted. And it's agreed to by plaintiffs. Whether Lupin is enjoined or not, Watson still has a right to go on the market. Enjoining Lupin does not mean that Shionogi will not face all of the generic competition problems that they claim are all going to flow from Lupin's presence. And in the binder that I gave to the Court this morning, there are -- we haven't gotten very little discovery, understandably, but the bit we have gotten, there are a series e-mails, two different groups of e-mails which show that Watson is getting ready to launch. They're preparing. There is an e-mail between Watson and Shionogi where they're splitting up what the ordered product Shionogi had ordered and they said, well, half of it goes to the brand and half of it is going to go to the generic and the market information as Mr. Hoffman said in his declaration, the market information is that Watson before the Standstill Agreement was out there talking to customers and promising them that they were going to be providing product. So whatever that might mean to whether if at the end of the day, we think unlikely, but if it should happen at the end of the day that the Court decides that Lupin does infringe a valid patent, and if at that point plaintiffs say well, you're responsible for the losses of our sales to Watson as well to you, maybe. But what it shows with respect to a preliminary injunction that the harm is going to happen whether Lupin's enjoined or not.

So there's no reason to have an injunction that's not going to be effective. It's going to hurt Lupin significantly and not help Shionogi.

THE COURT: Okay. Are you able to talk about the bond issue?

MS. JACOB: I haven't.

THE COURT: But you gave me about that much in the declaration.

MS. JACOB: Well, the declaration was based, we have four different possible scenarios about what might happen. We base your request for the bond on one year --

THE COURT: No, I don't mean to be critical. At least you addressed the bond. Plaintiff never did.

MS. JACOB: Well, your Honor, I hope that counts for us because obviously we're very unhappy to be discussing it all.

THE COURT: It has to be discussed. I mean whether you win or lose, we have to discuss it before I make a decision on this.

MS. JACOB: One year -- I have to look at it. But what we ask for the bond that we have of one year of what our profits would be if we were in the market by ourselves. If --

THE COURT: And why did you pick one year?

MS. JACOB: We picked one year in the hope that -- well, two reasons. One is because in about one year Mylan,

Mylan's 30 month stay expires. If they get final approval at that point, they would have an option of being able to launch. Well, it would just seem a time before which probably the parties would try to get the Court -- the case to trial. But that's why we figured one year.

THE COURT: You think it's going to take a year to get the case to trial?

MS. JACOB: I'm hoping sooner.

THE COURT: Any reason why it can't be sooner?

MS. JACOB: Because it always takes longer than we all hope. In this case we have not -- we had a Markman hearing, but we have not had -- we haven't had any fact discovery. I don't know the document production is pretty much complete, but I think the parties have to go back and revisit this. Despite the fact that we have expert declarations on this motion, we are haven't started expert discovery. We don't even have a scheduling order because this motion trumped our appointed meeting with Magistrate Judge Schneider. So, just being reasonable about it, it seemed to us that the chances of us getting a verdict by September, before September of 2012 weren't all that good. Plus that doesn't really take into account the time for appeal, but that should be considered as well. Our declaration, our -- Mr. Hoffman in sales at Lupin in his four different scenarios gave numbers for one year and then for the next year. So this

information if you think it's going to take longer for a two year bond. But I think to assume that it's going to be less than one year before this plays out and we can get back on the market if we're enjoined now is a little optimistic. And it's just to protect us for the damages, we would still have to prove obviously what our damages are. But my understanding is that the bond is based on we can collect.

THE COURT: Normally yes.

MS. JACOB: So if the bond is unduly low, it could be that Lupin would have damages that, not because we didn't ask for it. It just wasn't granted. We could not collect.

THE COURT: All right. Okay.

MS. JACOB: Your Honor, one of the points or a number of points, every point in my slide is very important. But would it make sense for me to go through the evidence that we have showing that market was declining? Showing that Shionogi --

THE COURT: No. I agree. I think the plaintiff agrees that the market was declining.

MS. JACOB: Okay.

THE COURT: You don't need to convince me of that.

MS. JACOB: One other thing. I think I did mention it to some extent, but the claims of the non-economic injury? But I just wanted to point out that Shionogi points to four non-economic harms. But there is really nothing in the record

that backs that up. In fact, to the contrary. They talk about the Japanese Parent might shift to another marketing partner. First the Crestor. Crestor was on the market. They were marketing it before they acquired Sciele which became Schionogi. So whatever their decision would have been, I don't think that's a particularly good piece of evidence that suggests that they're backing off according to Shionogi the annual report and the annual report for 2011 and the revised earning statement that they published on October 28th or October 31st. I don't remember if it's in the materials referred to, Organizational and Management Issues at Shionogi U.S. That they said they were taking steps to correct. So, one, it appears that the Japanese Parent is not backing off from its subsidiaries. And, two, they are aware there are problems there that they have corrected. They are correcting and presumably to go forward as they state in their annual report that they intend to go forward. And, in fact, in the October 2011 revised earning statement, financial statement, this was a month after Lupin had launched its generic competition and it's not mentioned. They don't point to that as being any sort of issue or any sort of problem, which is more of an indication of what we're saying that this is not an irreparable harm on Shionogi. Money damages at best. It's not really affecting their ability to go forward in all these non-economic ways that they've been pointing to.

THE COURT: Okay. Thank you.

MS. JACOB: Excuse me, your Honor. I have a little disappointment I wasn't able to run through my slides, but maybe the Court will look at it in chambers so it's not entirely lost. Thank you, your Honor.

THE COURT: Thank you very much. Did you want to add some things?

MR. HOCHSTETLER: Yes, Your Honor. Validity. May I discuss validity.

THE COURT: Please.

MR. HOCHSTETLER: Before I switch to that, one point I would like to make, your Honor, is clearly bothered by Lupin's package insert.

THE COURT: I'm not bothered by it.

MR. HOCHSTETLER: All right.

THE COURT: I'm not losing any sleep over it, I can tell you that.

MR. HOCHSTETLER: In the cases that plaintiff cites, in none of those cases did the Court ignore the actual test data on the product. They looked at package insert, but in every case they looked also at the test data that was available. And in this case, all the test data shows that Lupin's Tmax does not infringe. If your Honor were to find that the package insert means that Lupin does not have a substantial defense of non-infringement, you would be making a

groundbreaking decision, your Honor. I have several slides on validity, but let me do this. Let me summarize it quickly, and then I would like, if I could, take you through this small binder because what happened in the patent prosecution, I
03:03 believe the Court should understand and the Court can deduce what it wants to.

There's no dispute that our primary prior art is the same that was in front of the patent examiner. The difference is the law changed and the patent issued in 2005, the Supreme
03:03 Court issued the case KSR decision in 2007, and that is -- that's the C change, your Honor, with respect to how that prior art should be looked at. The Microsoft case also is important for understanding the presumption of validity as well. And with the Court's permission, I will address that
03:03 later, but I do want to make this point as strongly as I can.

The prior art references Cheng and Timmins were in front of the patent examiner. The issue of obviousness comes down to whether one with ordinary skill would be motivated to put them together to modify them. The Federal Circuit had a
03:04 fairly rigid test for determining that whether or not it should be combined. The KSR decision by the Supreme Court loosened that, made it more realistic. Make it more common sense. Our expert pointed out, for example, that a person with ordinary skill would have been motivated to modify it,
03:04 because the Timmins reference was Bristol Meyers who would

make the Gold Standard Glucophage product and they were the ones that had the Tmax of 8 and that would be motivation motivation. But the law changed, your Honor. So it's not -- this isn't a situation where you're revisiting what the 03:04 examiner did. With the law saying the same. The law is very different after KSR. But let me first throw -- if I could, let's go through the patent prosecution, if I may. And if you could pull the small binder out, your Honor, I would appreciate it. At the very beginning, your Honor, we have a 03:05 table of contents, and both Andrx and Lupin produced copies of it. We're going to work off of Lupin only because the two are identical, except Lupin's has and we produced it on the left hand side of the slide in front of you numbers of the documents, and that will help us go through and determine what 03:05 it is that happened during the prosecution.

So we'll start, your Honor, with Tab 12. You'll see that in the table of contents there's a reference to Amendment B dated March 4, 2003. You see that, your Honor?

THE COURT: Yes.

03:06 MR. HOCHSTETLER: Okay. And this was an Amendment submitted by the patent applicant. And you'll see that the document numbered line with the B lines up. And at the bottom of the, of the first page of the Amendment, you will see that the Tmax is five and a half to seven and a half hours after 03:06 administration following dinner. And this Amendment was an

effort to distinguish over the chain reference. As I mentioned earlier, your Honor, the chain reference gave the requisite Tmax after breakfast. So they limited the claims to the following day.

03:07 If your Honor would then go to Number 13. And the date on that is 5/21/03. And turn to the next page in the booklet, your Honor, you'll see that Document 13 dated 5/21/03 and it's an office communication. This was a rejection of the pending claims. And the claims were rejected as obvious. And they 03:07 were rejected as obvious in view of, among other things, change. So these are the claims that are in the issued patent right now. They were rejected as obvious. The only question is what happened next.

Go to Tab 14, your Honor. Document 14 is not 03:08 particularly important for our purposes. I'm just doing this for completeness. It refers to a -- an information disclosure statement.

Turn to the next page, you'll see the document Number 14. Document 15, however, your Honor, is important. Turn to 03:08 Tab 15. You will see that Tab 15, Document 15 refers to an interview summary dated November 20, 2003. You see that, your Honor?

THE COURT: Yes.

MR. HOCHSTETLER: All right. And if you turn to the 03:08 next page, Document 15 is an applicant initiated interview

request form. That's right up there. And the proposed date of the interview is November 20th. And the participants, talking about three participants. One is a Clifford Davidson who was the patent attorney for the plaintiff, and Thurman Page is the primary supervising examiner for the patent. You then turn to the next page, your Honor. This is the summary of the interview, and you'll see again on this page, and this is Andrx Document 202, under Tab 15. Are you with me, your Honor?

THE COURT: Yep.

MR. HOCHSTETLER: Okay. You'll see that, again you'll see again the participants in the interview was Mr. Davidson, there's a Mr. Whitlock and Mr. Page. The date of the interview is November 20th. And the description of the subject matter is recorded. Importance of Tmax presented and the relationship with gluconeogenesis. Closest prior art suggest that general teaching of the Tmax of 8. Applicant to request reconsideration and reconsideration to be given in view of the working examples.

Okay. Now, your Honor, we go to the somewhat orderly numbered Document, 15 and a half. And I think you'll see what happened and why it has the odd number in a moment. We're going to end and then come back to this document twice. The -- if you can turn to the first page in the Tab behind Tab 15, your Honor, you will see a facsimile page.

THE COURT: Yes.

MR. HOCHSTETLER: But what I wanted you to see for right now is Document 15 and a half involved an Amendment of all of the claims. This is dated November 21, 2003, one after 03:11 the interview. Claim one is a seven and a half in Claims 2 and 3 and 4 are all cancelled. In Claim 5 is rewritten. And the upper limit of the Tmax and all the claims is now changed to seven. Also -- this is the day after the interview, Judge. This would be the next page I think in the Tab, your Honor. 03:12 Highlighted it.

The undersigned gratefully acknowledges the courtesies extended by Supervisory Examiner Page to the undersigned and Ted Whitlock, Esquire during the interview conducted at the USPTO on November 20th, 2003. And then proceed to describe 03:12 the interview, your Honor. And on Page 272 which is on the screen now. He reports what happened during the interview. This is the next day. And it says:

The examiner considered the closest prior art to Tmax of 8. The examiner agreed that Tmax of 7 would be patentable. 03:13 The examiner agreed to consider the patentability of seven and a half if applicants were to provide a working example of that value as well. And then the next sentence.

In view of the deadline for filing this response, claim 1 has been cancelled. In other words, they provided no 03:13 working example. And they limited all of the claims to a Tmax

of 7, or so they thought.

Turn now to Tab 16, your Honor. We're going to come back to this document. This is the notice of allowance document, number 16, December 19th, 2003. And it says that the claims were allowed, including the claims that we just saw have been cancelled. You'll notice on the Notice Allowability it says: This communication is responsive to interview conducted November 20th, 2003. There is no reference to the Amendment submitted the next day in which the claims were changed.

Now this is kind of where the plaintiff would like to stop. But we see a lot more, Judge, as we go through the prosecution.

The next document Tab 17 is for this purpose not a particularly relevant document, your Honor. Just for purposes of completeness. You'll see behind the Tab is document number 17 with the same date. But document number 18, your Honor, is important. Document number 18 now this is dated January 8, 2004, and it's request corrected notice. And you'll see if you turn the tab, your Honor, this is number 18 requesting corrective notice. And this is written about by Mr. Davidson who is involved in that interview. And he said:

A notice of allowance for the above referenced application was mailed on December 19, 2003. Just a couple weeks before. Upon review of the Notice of Allowability and

accompanying documents, Applicant's attorney determined that certain claims that were indicated as allowable were cancelled. For example, claims 1 and 4 and certain claims which were pending, claims 30 and 43 were not acknowledged in the Notice of Allowance. As required by the examiner, he continues, a listing of the pending claims is provided below. And then further on, Judge, are the new claims. And you'll see, Judge, claim 7, Tmax of 7 is the maximum on all of these claims. And then at the end, this man who was in the interview with the examiner says: Applicants respectfully request that the examiner provide a supplemental notice of allowance indicating the properly allowed claims.

May I go to the next tab?

THE COURT: Yes, please.

MR. HOCHSTETLER: Tab 19, your Honor. This is only four days later, January 12th. The patent applicant is asking again in response to the Notice of Allowance dated December 19, 2003. Applicants respectfully request that the following claim set be published in the printed patent. And the patent -- and the claims follow, your Honor, and a Tmax of 7 is the maximum of all the claims. All of these claims were changed. That was the November 21st amendment purported to change all of the claims. So that a Tmax of 7 was the maximum. All of the claims were changed. And even claim 5 was changed as well. Now that's also in January.

Now, your Honor, if you would go back to 15 and a half.

THE COURT: All right.

MR. HOCHSTETLER: You can now see what probably happens. Why is it 15 and a half? Because it got squeezed in. If you look at the page after, what you see is that in the opening fax as requested by examiner Micah Paul Young. Transmitted herewith is a duplicate copy of the Amendment filed on November 21, 2003 in the above identified case and the postcard stamped by the USPTO. He wanted the postcard to show that, in fact, that amount had been received by USPTO. And that November 21st amendment, and this is dated September, September 04, your Honor. And this is again the November 21st amendment is changed. All of the claims, all the claims are changed to specify a maximum of seven hours. And then you see kind of scribbled here, your Honor, on this page. This would be page AND265. That's I believe what it says, your Honor, is okay to enter MPY. That's the examiner Micah Paul Young 11/29/04.

Now if you then turn to Tab 20, your Honor. You will see a Supplemental Notice of Allowance dated 11/30/04. And now the claims that were amended on November 21st, 03 are being allowed. And the Notice, the Notice of, Supplemental Notice of Allowability. If you'll look at the bottom of it, your Honor. A Thurman Page signature and he signed off on that. His signature. But for reasons that aren't entirely

clear, the Patent Office Printing Department apparently printed the claims from the first Notice of Allowance, not the second.

Now, the plaintiff has posited from parts of this story that the examiner must have after the interview thought, well, I guess maybe a Tmax of seven and a half would be okay to allow them after all. But the patent attorney didn't think. He kept coming back to change it. The patent attorney talked to the examiner and the examiner signed off on the Supplemental Notice. And if the Patent Office had done what it should have done, we would be fighting about a patent with a Tmax of 7 rather than seven and a half.

Your Honor, I've never encountered a situation like this, and I don't believe our expert has either. But we have here a patent where the claims are not what the patent examiner intended to allow, and not what the patent attorney thought they were entitled to. So the irony here is on the presumption of validity is based on the presumption of administrative regularity. But here we have evidence in the documents that shows that the PTO's administrative process was not regulated in this case. We're being sued on a patent that the patent examiners did not intend to be in this patent.

THE COURT: Okay. Thank you. You have five minutes to respond, at most.

MR. BASSETT: Thank you, your Honor. I'll go right

to the final point. Spent a lot of time going through this file history. It is irregular. I never seen anything like it myself either, your Honor. But several points. There's no dispute that the upper limit is 7.0 is supposed to be in there. Lupin still loses. They still infringe. Their label still says that they fall within the range to have the upper limit of 7.0. So all of that argument substantively means nothing.

Secondly, your Honor, to the extent there was a printing error, this Court can correct it. So, that's not -- that doesn't invalidate a patent. That simply is a ministerial issue that can be corrected. Claim 3 of this patent has an upper limit of 7.0. No dispute that that's what the claim, upper claim limit should have been. And there's no dispute that their label says that they fall within it. I don't think that's -- I think all of this is an issue that means nothing.

Secondly, they still can't dispute the fact that the examiner on December 19th allowed the claims with a 7.5 upper limit. That's what the examiner substantively intended. These other things were procedural issues that had to do with a deadline that they were afraid that they blew up as of November 21st and they wanted to fix it. It has nothing to do with the substantive point, your Honor.

I am impressed when Lupin continues to push this

argument that the Court should simply ignore what's in their label. I think the only point that I would add to what we've already argued is that Lupin continues to suggest that it must have copied the label. It was required to copy the label. He was only required to copy the label, let's be honest, so it could get into the market and make money. It wanted to enter the market. So it copied the label. That doesn't mean it was appropriate for them to do so. I cannot believe that they think that it's appropriate to include in their label something that they think is inaccurate in order to get that claim to get the label approved. That they have to be able to come into this Court and argue that we shouldn't be able to prove infringement because that label is inaccurate. That can't be an appropriate standard and an appropriate argument. And I don't, I would suggest that I don't think the Court should countenance that kind of argument. They never gave the FDA the opportunity to evaluate whether the Tmax was appropriate or not. They could have. There's procedures in place to do it. They chose not to do it because they wanted to be able to sell their product and make money. It wasn't because they were required to do so by the regulation.

I think with that, your Honor, I would stop, unless you have any questions.

THE COURT: I don't. Thank you.

MR. BASSETT: Thank you very much.

THE COURT: All right. Well, I know I told you at the beginning that I was prepared to rule today. I am not. But we will have a decision out Monday or Tuesday of next week. I'll get to it as fast I can. I have other things that
03:26 I'm involved with at the moment, and for the rest of the afternoon I'm in the middle of a complex trial, criminal trial next week also. So, but we'll get this out Monday or Tuesday of next week.

MR. BASSETT: I appreciate that, your Honor. The
03:27 only issue that I would raise is that the Standstill Agreement expires at midnight tonight. Could that be extended until the Court issues the ruling?

MS. JACOB: Your Honor, as I did before the phone conversation, I have also discussed this with my client before
03:27 we came in and Lupin is willing to extend the Standstill through next week to give the Court an opportunity to decide.

THE COURT: Thank you.

MR. BASSETT: I appreciate that. Thank you.

THE COURT: Thank you for your presentations,
03:27 counsel. If I do grant the request for the injunction, and feel it necessary to have a bond hearing, it would be at the end of next week sometime. I'm not sure I need any other information, but let me look into that. And, of course, you still have to prevail.

03:27 MR. BASSETT: Understood.

THE COURT: Thank you, everybody. We'll talk to you soon. Where do you want to go from here, or do you want time to think about whether you want me to send this back to a Delaware Judge or do you want me to keep this?

03:28 MR. BASSETT: Your Honor, I haven't had a chance to discuss this, but from our perspective, I think we would be perfectly happy staying here with your Honor.

MR. HOCHSTETLER: We have not had an opportunity to confer with our client and we would respectfully would like

03:28 that opportunity.

THE COURT: Sure. Why don't you do that. Everybody do that and just send me letters as to what you feel about how you want to proceed. I mean it's unusual that you get an opportunity to Judge shop, but here you have it.

03:28 MR. HOCHSTETLER: May I say one thing in response to Mr. Bassett?

THE COURT: No. Thank you. No.

MR. HOCHSTETLER: Okay.

THE COURT: No. Trust me. I read your papers before

03:28 today. I know what your arguments are. Thank you very much, everybody.

(The matter was then concluded)

C E R T I F I C A T E.

I, **Carl J. Nami, C.S.R.,** Official United States Court Reporter and Certified Shorthand Reporter of the State of New Jersey, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth.

I do further certify that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel and that I am not financially interested in this action.

S/Carl J. Nami, CSR_____

CARL J. NAMI, C.S.R.

Certificate No. 557

Date: December 28, 2011

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